

that of salbutamol. The Examiner asserts that Sykes describes formoterol being "used as a patient's approach in treating their asthma by taking an extra dose when needed." The Examiner concludes that, in combination, these references would have led the artisan to use the budesonide/formoterol combination of Carling on an as needed basis.

Applicant traverses this rejection on several grounds.

First, the study described by Vanzieleghem involved nasal inhalation for treatment of allergic rhinitis, and provides no suggestion that a similar mode of administration ("as needed" administration) would be suitable for use in treating asthma by oral inhalation. Allergic rhinitis and asthma are different conditions, involving different symptoms and different parts of the respiratory tract. It would not have been obvious to the artisan that a therapy that might be successful in treating symptoms of allergic rhinitis, e.g., sneezing and runny nose, would be effective as a rescue medication for a patient suffering from an asthma attack.

Second, Applicant does not agree that the Sykes study involved instructing the participants to "take an extra dose when needed." Instead, the abstract merely states that one of the calculation methods used in the study reflected the tendency of some patients to do this with asthma medication. Moreover, although the Examiner is correct that the abstract suggests that older patients should take the medication "8 hourly," this is irrelevant, since instructing a patient to take a medication regularly on an "8 hourly" basis is very different from instructing the patient to take the medication as needed, based on the patient's own assessment of his or her symptoms.

Thus, neither of these references would have fairly suggested instructing the patient to inhale the Carling composition on demand, as determined by the patient based on the patient's symptoms, to provide short-term relief of asthma symptoms. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Applicant : Tommy Ekström  
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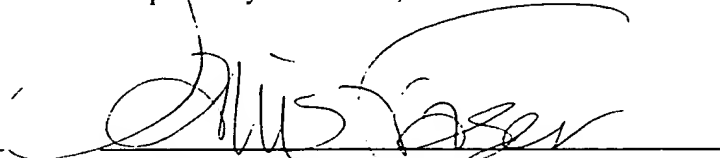
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Applicant asks that all claims be allowed. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

Dec. 26, 2001



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